

K905468 PYLORI-G FIAX TEST KITMay 7, 1991
152 days to decisionK905468 · Product code: LYR · Microbiology
Source: <https://www.510kdatabase.net/k905468/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Helicobacter Pylori (LYR)
Date received	Dec 6, 1990
Decision date	May 7, 1991
Days to decision	152 days
Third-party review	No

APPLICANT

Company	Whittaker Bioproducts, Inc.
Location	Walkersville, MD, US
Contact	LEIF E OLSEN
510(k) history	30 submissions · 30 cleared · 1984-1992

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